

## METHOD AND APPARATUS FOR TREPHINATING BODY VESSELS AND HOLLOW ORGAN WALLS

### Field of the Invention

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The field of this invention is surgery and especially, cardiovascular, general or peripheral vascular surgery.

### Background of the Invention

During surgical procedures such as placement of a ventricular assist device, blood vessel anastomosis, aortotomy, gastrotomy, enterotomy, or access to other hollow organs and vessels, it is useful to have a specialized tool to create a circular opening or fenestration in the wall of the vessel or organ. Punches have been developed for use in surgery that create such fenestrations. Examples of the prior art include US patent number 3,949,747 to Hevesy, US patent number 4,018,228 to Goosen, US patent number 4,122,855 to Tezel, US patent number 4,216,776 to Downie et al., US patent number 5,129,913 to Ruppert, US patent number 5,827,316 to Young et al., US patent number 5,910,153 to Mayenberger, and US patent number 5,972,014 to Nevins. More recent patents include US patent number 6,080,173 to Williamson IV et al., US patent number 6,080,176 to Young, US patent number

6,176,867 to Wright, and US patent number 6,187,022 to Alexander Jr. et al.

Problems with the current punches or coring devices occur both when the punch is positioned and actuated. With current systems, the cutting occurs by application of manual force by the surgeon. By requiring manual force to punch the hole in the organ or vessel wall without an adequate point of reference, the surgeon is not able to ascertain that the hole will be created along the correct path and at the selected location, prior to actually punching the hole. In addition, the current punches operate by means of a die without opposing back-up-plate cutting members. Examples of current punch mechanisms are similar to scissors where the cutting blade passes by an opposing brace or other cutting blade. These systems all create suboptimal openings and leave ragged tissue edges.

New devices and methods are needed which facilitate creation of a hole in the hollow organ or vessel and allow confirmation of proper location, orientation, and coring path prior to actual creation of the hole in the hollow organ or vessel wall. In addition, devices are needed to make more precise, cleaner holes in the tissue. Such cleaner holes allow for more precise surgery, more

controlled placement of anastomoses, more control over surgically created geometry, reduced blood loss and resultant improved patient outcome.

Summary of the Invention

5        This invention relates to a trephine, coring tool, or  
punch for creating a hole or stoma at a precise, desired  
location in a hollow organ or body vessel. The present  
invention is a cutting surface that is opposed by an anvil  
to create a clean cut. The anvil comprises a tapered nose  
10      to facilitate penetration into the organ or vessel once a  
preliminary incision has been performed. The cutting  
surface is spring loaded to perform the actual cutting  
under pre-assigned force. The system allows for location  
reference by allowing the punch to rest, under spring  
15      force, against the tissue to be cut while final alignment  
is completed, thus allowing a more accurate cut.

In the prior art previously cited US patent number  
4,018,228 to Goosen, US patent number 4,216,776 to Downie  
et al., US patent number 5,129,913 to Ruppert, US patent  
20      number 5,827,316 to Young et al., US patent number  
5,910,153 to Mayenberger, US patent number 5,972,014 to  
Nevins, US patent number 6,080,173 to Williamson IV et al.,

and US patent number 6,080176 to Young use a shearing or scissoring action between two blades to cut tissue. US patent number 3,949,855 to Hevesy, US patent number 4,122,855 to Tezel, and US patent number 6,187,022 to 5 Alexander et al. use a knife or single sharpened edge with no opposing blade or surface to cut tissue. Both of these methods produce a ragged cut. The present invention distinguishes over the cited prior art because the tissue is cut between a sharp edge and an opposing, flat, anvil-like surface to produce a clean cut.

The invention is most useful in cardiac surgery to create an opening or channel for cannula access to the ventricles of the heart or blood vessels near the heart. It is also useful for vascular surgery where side-to-side 15 or end-to-side anastomoses need to be made. Alternatively, the system allows for general tissue biopsies and other general surgical applications on hollow organs or vessels such as a tracheostomy.

#### Brief Description of the Drawings

20 Figure 1A illustrates a side view of the trephine, punch or coring tool of the current invention with the cutter fully retracted.

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*A.*

Figure 1B illustrates a side view of the trephine, punch or coring tool of the current invention with the cutter fully advanced against the anvil.

5 Figure 2 illustrates the trephine, punch or coring tool applied to the apex of the ventricle of the heart prior to advancing the cutting blade.

10 Figure 3 illustrates the trephine, punch or coring tool after the blade has been advanced through the apex of the ventricular wall of the heart.

15 Figure 4 illustrates the ventricular wall after removal of the trephine, punch or coring tool and the excised tissue.

Figure 5A illustrates another embodiment of a side view of the trephine, punch or coring tool with the anvil fully advanced.

Figure 5B illustrates a side view of the trephine, punch or coring tool with the anvil fully retracted against the cutter.

Detailed Description of the Invention

Figure 1A illustrates a hollow organ coring tool, trephine, or punch 10 of the present invention. The coring tool 10 comprises a cutter 12, a central axially elongated shaft 14, an anvil 16, a trocar or tapered tip 18, a handle 20, a spring 22, and a knob 24. The cutter 12 comprises a plurality of holes 28. The handle 20 further comprises a plurality of wide flange-like members or wings 26. The handle 20 optionally comprises a setscrew 30. The cutter 12, the anvil 16, the trocar or tapered tip 18, the handle 20, the spring 22, and the knob 24 are disposed concentrically on the axially elongate shaft 14. The knob 24 is affixed to the proximal end of the shaft 14. The handle 20 is affixed to the cutter 12 with the optional setscrew 30. The handle 20 and attached cutter 12 slide rotationally and longitudinally in a one to one motion along and around the shaft 14. The spring 22 is slidably disposed between the knob 24 and the handle 20 and imparts a pre-determined force on the handle 20-cutter 12 assembly.

The anvil 16 is affixed to the proximal end of the trocar or tip 18 and the tip 18 is affixed to the distal end of the shaft 14.

Figure 1A shows the coring tool 10 with the cutter 12 in the fully retracted position. The cutter 12 is a cylindrical blade made from materials capable of being sharpened and with a high degree of hardness. Such 5 materials include but are not limited to stainless steel, cobalt-nickel-chrome alloys, titanium alloys and the like. The cutter 12 has a sharpened configuration on its distal most edge to permit surgical cutting of body tissue. The distal cutting edge of the cutter 12 is, preferably, smooth 10 but sharpened. Alternatively, the distal cutting edge may be serrated like a bread knife. The hollow interior of the cutter 12 is sufficiently long to allow the cored-out tissue to reside therein without being compressed. Holes 15 28 are optionally provided in the proximal end or sides of the cutter 12 to allow for fluid escape during cutting, thus preventing pressure buildup within the cutter 12. The cutter 12 may be any diameter necessary for the surgical procedure. The diameter of the cutter 12 ranges from 0.5mm 20 to 100mm or even larger with the diameter range preferably being from 1mm to 50mm.

In another embodiment, the cutter 12 may be an electrocautery or electrocutting device consisting of an electrode. The electrode is electrically connected to a

cable leading to one pole of an external electrocautery power supply. Another electrical pole of the power supply is an electrically conducting grounding pad electrically affixed to the patient's skin or other body organ, often 5 with the aid of electrically conducting gel.

In a further embodiment, the cutter 12 may be rotationally vibrated using an electrical motor or one or more electrical actuators. Examples of electrical actuators include those fabricated from shape-memory 10 nitinol with or without an elastic substrate. Ohmic heating of the nitinol actuators by application of electrical current causes reversible length change in said actuators. Opposably mounted actuators, energized one at a time, provide torque to rotationally vibrate the cutter 12 15 about the shaft 14. The actuators and cutter 12 operate at frequencies up to about 200 Hz. Electrical current is provided through an electrical cable leading to an external set of batteries and a controller. Alternatively, said controller and batteries could be mounted integral to the 20 coring tool 10, such as in the knob 24, for example. Such rotational vibration makes the cutter 12 function like an electric bread knife with enhanced cutting capability over a stationary knife-edge.

In a preferred embodiment, the handle 20 is affixed to the cutter 12. The handle 20 provides rotational force to the cutter 12 to assist in tissue penetration. The optional setscrew 30 may be used to attach the handle 20 to the cutter 12. Other ways to attach the handle 20 to the cutter 12 are the use of a rolled-pin, adhesives or over-molding. Mechanical advantage for manual rotation is derived from the wide flange like members or wings 26 on the handle 20 that allow increased moment arm to be applied to the handle 20 by the fingers of the surgeon. The handle 20 is preferably made from polymers such as but not limited to polycarbonate, acetal copolymers, acrylnitrile butadiene styrene, polyvinyl chloride and the like. The handle 20 optionally is provided with holes or openings that communicate with the optional holes 28 in the cutter 12 to allow for air and fluid escape from the interior of the cutter 12 through the handle 20 to the external environment during the coring process.

Optionally, the handle 20 comprises a latch or lock to maintain its position on shaft 14 in the retracted position under force of the spring 22. To move the handle 20 distally, the optional lock is released allowing the handle 20 to be advanced along the shaft 14 toward the anvil 16.

The handle 20 further optionally comprises a damper or shock absorber to prevent the high velocity accidental release of the handle 20 and cutter 12 into the tissue.

- 1C2* Alternatively, the handle 20 may be rotated by a motor or gear motor which is electrically powered by a battery disposed either external to or internal to the punch 10. External battery power is delivered to the motor through a cable with a plurality of conductors. On and off operation of the motor is controlled through a switch on the punch 10 knob 24 or the handle 20, by a foot switch, or by a sound activated switch.

- Figure 1B shows the handle 20-cutter 12 assembly fully advanced against the anvil 16. The spring 22 is disposed between the knob 24 and the handle 20 and applies the desired force to the handle 20-cutter 12 assembly distally toward the anvil 16 with a pre-determined force. The pre-determined force is between 0.10 and 25 pounds and, preferably, between 1 and 10 pounds. This force is advantageous in performing a controlled tissue excision.
- The spring 22 also allows the cutter 12 to be disposed against the tissue prior to actual excision, without cutting, so that correct alignment may be determined by the surgeon. The spring 22 is, preferably, made from spring

hardened metals such as stainless steel 304, stainless steel 316, nitinol, titanium alloys and the like. The spring 22 ensures that a seal is maintained between the cutter 12 and the tissue so that hemostasis is maximized or 5 leakage of body fluids is minimized.

~~C3~~ In another embodiment, the function of the spring 20 is replaced by a threaded jackscrew assembly. The shaft 14 is threaded and engages mating threads on the handle 20. By rotating the handle 20, the cutter 12 is rotated and 10 simultaneously advanced proximally or distally in a positive displacement fashion.

~~C4~~ In yet another embodiment, the function of the spring 20 is replaced by a hydraulic cylinder and hydraulic pressure source with a valve or switch to control pressure 15 into said cylinder.

The central shaft 14 maintains axial and longitudinal orientation of the punch 10 components. The shaft 14 is preferably fabricated from metals such as stainless steel, cobalt-nickel-chrome alloys, titanium alloys and the like.

20 The shaft 14 may also be fabricated from hardened polymers such as glass-filled polycarbonate and the like. Holes or circumferential depressions in the shaft 14 permit

attachment of components using setscrews or over-molding techniques. The shaft 14 geometry allows for expeditious replacement of optionally disposable components such as the cutter 12, anvil 16 and tip 18. The central shaft 14, 5 optionally, comprises one or more circumferential alignment marks to confirm the cutter 12 position from the proximal end of the punch 10.

*(C5)* The tapered tip 18 is affixed to the distal end of the shaft 14 in a stationary manner. Fixation of the tip 18 to 10 the shaft 14 is accomplished by over-molding, a setscrew or by internal threads on the trocar or tapered tip 18 engaging male threads on the shaft 14. The trocar or tapered tip 18 has a conical configuration and allows penetration of the hollow organ or vessel by the entire tip 15 18 anvil 16 assembly following an initial incision with a sharp surgical instrument. The distal end of the trocar 18 may be either sharp or rounded. Use of the sharp end on the trocar 18 permits use of the coring tool 10 without first making a separate surgical incision in the tissue. 20 Longitudinal edges are optionally disposed on the conical surface of trocar or tip 18 to enhance tissue penetration. Alternatively, the tip 18 may be oscillated or vibrated with an electrical actuator or motor to facilitate

penetration into the tissue. The oscillation is useful for either blunt dissection or sharp dissection of the tissue.

The anvil 16 is a flat surface disposed distally to the cutter 12 and aligned in a plane generally perpendicular to the axis of the shaft 14. The anvil 16 is at least as wide as the largest exterior cutting dimension of the cutter 12. In this way, the anvil 16 serves to positively stop the cutter 12. The cutter 12 is advanced against the anvil 16 during the cutting procedure. The cutter 12 does not pass beyond the proximal surface of the anvil 16. In its lowest energy or inactive state, the cutter 12 rests against the anvil 16 with a net compressive force and the spring 22 expanded to its maximum allowable amount. The compressive force between the closed cutter 12 and the anvil 16 serves to maintain contact between the surfaces and promote cutting at the end of the stroke.

The anvil 16 and the tapered tip 18 are, preferably fabricated from the same piece of material for economy and ease of fabrication. Alternatively, the anvil 16 and the tapered tip 18 may be separate components and may be longitudinally disconnected or they may be longitudinally connected. Both the anvil 16 and the trocar or tapered tip 18 are radially constrained by the shaft 14. The anvil 16

is attached to shaft 14 by a setscrew, internal threads for engagement with male threads on the shaft 14, adhesive bonding or over-molding. The anvil 16 and the trocar or tapered tip 18 are, preferably, fabricated from polymeric materials such as but not limited to polyvinyl chloride, acetal copolymers, polycarbonate, acrylinitrile butadiene styrene and the like. They may alternatively be fabricated from metals such as stainless steel, cobalt-chrome-nickel alloys, titanium alloys and the like.

10       The anvil 16 optionally comprises pre-placed attachment devices, such as staples, sutures or posts that remain in the tissue around the coring site to facilitate subsequent placement of anastomotic devices.

15       The knob 24 terminates the proximal end of the shaft 14 and allows for positioning of the punch 10 by the surgeon. The knob 24 is blunt and preferably is fabricated from the same materials as the trocar or tip 18 or the anvil 16. The knob 24 is affixed to the shaft 14 with setscrews, adhesives, or over-molding or the knob 24 is 20 affixed by female threads that engage male threads on the shaft 14.

Referring to Figures 2,3, and 4, the procedure for hollow organ coring or trephination is accomplished by first creating a small incision at the desired penetration location using a sharp surgical instrument such as a scalpel. The cutter 12 is retracted by manually withdrawing the handle 20 wings 26 proximally toward the knob 24. The spring 22 is compressed when retracting the handle 20 and cutter 12. The tapered tip 18 and anvil 16 assembly is advanced into the incision until the anvil 16 has passed beyond the interior surface of the hollow organ or vessel. The handle 20 is next released and the cutter 12 is positioned against the exterior of the hollow organ as shown in Figure 2. Once position has been confirmed or adjusted, the handle 20 is manually rotated to initiate cutting of the tissue by the cylindrical cutter 12. As shown in Figure 3, the handle 20 and cutter 12 are rotated until full penetration of the hollow organ has occurred, under force of the spring 22, and the distal edge of the cutter 12 rests against the anvil 16.

Complete penetration and cutter 12 to anvil 16 contact may be confirmed by placement of a plurality of alignment marks on the shaft 14. The alignment marks become visible once the cutter 12 and handle 20 have been advanced

sufficiently. The punch 10 is next withdrawn proximally, removing the cored-out piece of tissue from the organ as shown in Figure 4. Prevention of hemorrhage or fluid leakage from the hollow organ or vessel is accomplished by 5 manual compression or placement of a temporary plug. This device and procedure are especially useful when performing coring on the beating heart.

Typically, the surgeon manually cores the patient's hollow organ or vessel using the punch or coring tool 10. 10 The coring tool 10 could, alternatively, be held and manipulated by a robotic arm or laparoscopic instrument.

Figures 5A and 5B illustrate another embodiment of a hollow organ coring tool, trephine, or punch 38. The coring tool 38 comprises the cutter 12, the anvil 16, the 15 trocar or tapered tip 18, the handle 20, the spring 22, and the knob 24. The coring tool 38 also comprises an inner shaft 32, an outer shaft 34, a pin 36, and an axial slot 40. The handle 20 further comprises the plurality of wide flange-like members or wings 26.

20 The cutter 12, the handle 20, the spring 22, and the knob 24 are disposed concentrically on the axially elongate outer shaft 34. The anvil 16 and the trocar or tip 18 are

disposed concentrically on the axially elongate inner shaft

32. The inner shaft 32 is slidably disposed inside the outer shaft 34 and the inner shaft 32 extends beyond the outer shaft 34 at least the thickness of the vessel or

5 organ to be cored.

The handle 20 is not affixed to the cutter 12.

Instead, the handle 20 is affixed to the inner shaft 32 by the pin 36 through the axial slot 40 in the outer shaft 34.

10 The cutter 12 is affixed to the distal end of the outer

shaft 34. The handle 20, which is affixed to the inner shaft 32, sets above the cutter 12, which is affixed to the outer shaft 34.

The knob 24 is affixed to the proximal end of the outer shaft 34. The anvil 16 is affixed to the proximal

15 end of the trocar or tip 18 and the tip 18 is affixed to the distal end of the inner shaft 32.

The spring 22 sets around the outer shaft 34, between the knob 24 and the handle 20. The spring 22 forces the tip 18 and anvil 16 distally away from the cutter 12.

20 Manual retraction of the handle 20 proximally causes proximal retraction of the anvil 16 toward the cutter 12.

The spring 22 becomes increasingly compressed as the handle 20 is moved proximally toward the knob 24.

Referring to Figure 5A, the handle 20, the tip 18, the anvil 16, and inner shaft 32 of the trephine 38 are fully advanced. The spring 22 is not compressed and is in its lowest energy position. The pin 36 rests in the distal end of the slot 40 and prevents the handle 20, the tip 18 and the anvil 16 from advancing further.

The handle 20 or the knob 24 optionally comprise a lock that is manually operated and selectively prevents movement of the inner shaft 32 relative to the outer shaft 34.

Referring to Figure 5B, the handle 20, the tip 18, the anvil 16, and the inner shaft 32 are fully retracted. The spring 22 is fully compressed and in its highest energy position. Retraction of the handle 20 is accomplished with one hand over the knob 24 and fingers wrapped around the wings 26 in the handle 20. Pulling the fingers toward the knob 24 causes the anvil 16 to move proximally toward the cutter 12. The movement stops when the anvil 16 meets the cutter 12.

The procedure for hollow organ coring or trephination is accomplished by first creating a small incision at the desired penetration location using a sharp surgical instrument such as a scalpel. The tapered tip 18 and anvil 5 16 assembly is advanced into the incision until the anvil 16 has passed beyond the interior surface of the hollow organ or vessel and the cutter 12 rests on the exterior of the hollow organ or vessel. Once position has been confirmed or adjusted, the handle 20 is pulled toward the 10 knob 24 to initiate cutting of the tissue by the circular cutter 12. The handle 20 is pulled until the distal edge of the cutter 12 rests against the anvil 16 and the organ has been cored. Complete penetration and cutter 12 to anvil 16 contact may be confirmed by placement of a 15 plurality of alignment marks on the outer shaft 34. The alignment marks become visible once the anvil 16 and the handle 20 have been retracted sufficiently. The punch 38 is next withdrawn proximally, removing the cored-out piece of tissue from the organ.

20 The hollow organ coring tool, trephine, or punch 38 is fabricated from the same materials as the hollow organ coring tool, trephine, or punch 10 and comprises the same or similar options as the hollow organ coring tool,

trephine, or punch 10. For example, the cutter 12 of the punch 38 may be rotated by a motor or actuator to facilitate tissue penetration.

The present invention may be embodied in other  
5 specific forms without departing from its spirit or  
essential characteristics. The described embodiments are  
to be considered in all respects only as illustrative and  
not restrictive. The scope of the invention is therefore  
indicated by the appended claims rather than the foregoing  
10 description. All changes that come within the meaning and  
range of equivalency of the claims are to be embraced  
within their scope.

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